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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

		Application Number	10/803,145
		Filing Date	March 17, 2004
		First Named Inventor	Karen Seibert
		Art Unit	1617
		Examiner Name	Jiang Shaojia
Total Number of Pages in This Submission	-	Attorney Docket Number	27880A/USA 15071/USA 6794-000177/US

ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to Technology Center (TC)
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment / Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Form HDP-1449 38 References Return Receipt Postcard
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Certified Copy of Priority Document(s)	Remarks	
<input type="checkbox"/> Response to Missing Parts/ Incomplete Application		
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Harness, Dickey & Pierce, P.L.C.	Attorney Name	Reg. No.
		James E. Davis	47,516
Signature			
Date	May 12, 2005		

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Assignment Recordation Services, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name	James E. Davis	Express Mail Label No.	EV 914261062 US
Signature		Date	May 12, 2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/803,145

Filing Date: 03/17/2004

Applicant: Karen Seibert

Group Art Unit: 1617

Examiner: Jiang Shaojia

Title: Method of providing a steroid-sparing benefit with a cyclooxygenase-2 inhibitor and compositions

Attorney Docket: 1507/1/US; 27880A/USA (6794-000177/US)

Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicant hereby submits an Supplemental Information Disclosure Statement for consideration by the Examiner.

I. **LIST OF PATENTS, PUBLICATIONS, AND OTHER INFORMATION**

The patents, publications and other information requested to be considered by the Office (except unpublished U.S. patent applications) are listed on Form 1449 attached hereto.

II. **COPIES**

A. Submitted herewith is a legible copy of (i) each foreign patent; (ii) each publication or that portion which caused it to be listed, other than U.S. patents and U.S. patent application publications unless required by the Office; (iii) each unpublished U.S. application listed below in Section IV (i.e., including the specification, claims, and any drawing of the application, or that portion of the application which caused it to be listed, including any claims directed to that portion), except for such applications filed on or after June 30, 2003, pursuant to the Waiver of the Copy Requirement in 37 C.F.R. 1.98 (OG Notice dated October 19, 2004); and (iv) all other information or that portion which caused it to be listed.

B. Any patents, publications or other information which are listed on Form 1449 or on the copies of PTO-892, but which are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Serial Number

U.S. Filing Date

C. This is a PCT application in the entry of the National Phase in the United States. A copy of the International Search Report is attached for the Examiner's information. The documents listed on the International Search report are listed on the attached Form 1449 for consideration by the Examiner and for listing on any patent resulting from this application. If the International Search report was from the US, EPO, or JPO search authorities, copies of these references should have been supplied to the USPTO under the trilateral agreement and are believed to be in the file of the above-identified application. (MPEP 1893.03(g).)

III. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

A. Except as may be indicated below in (B), all of the patents, publications or other information are in the English language (concise explanation not required).

B. A concise explanation of the relevance of each patent, publication or other information listed that is not in the English language is as follows (see 37 C.F.R. § 1.98(a)(3)):

1. See the attached foreign patent office communication from a counterpart foreign application:

2. English translations are provided:

3. Other:

C. The following additional information is provided for the Examiner's consideration.

IV. CROSS REFERENCE TO RELATED APPLICATION(S)

A. The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this(these) application(s) to the Examiner's attention, Applicant(s) does (do) not waive the confidentiality provisions of 35 U.S.C. § 122.

<u>Serial No.</u>	<u>Filing Date</u>	<u>Art Unit</u>
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V. THIS IDS IS BEING FILED UNDER

A. **37 C.F.R. § 1.97(b): (check only one box)**

1. within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. § 1.97(b)(1)). No fee or certification is required.
2. within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or certification is required.
3. before the mailing of a first Office Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below; or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).
4. before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No fee or certification is required.

B. **37 C.F.R. § 1.97(c): (check only one box)**

before the mailing date of either any Final Office Action under 37 C.F.R. § 1.113, a Notice of Allowance under 37 C.F.R. § 1.311, or an action that otherwise closes prosecution.

1. No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).
2. See the certification below. No fee is required.

C. **37 C.F.R. § 1.97(d):**

after the mailing date of either a Final Office Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311, yet on or before payment of the issue fee.

1. See the certification below. A fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

VI. **CERTIFICATION UNDER 37 C.F.R. § 1.97(e):** (check only one box)

The undersigned hereby certifies that:

A. each item of information contained in this IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(1)). See further statement under 37 C.F.R. 1.704(d) below in section VII, if applicable; or

B. no item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(2)).

C. some of the items of information were first cited in a communication from a foreign patent office. As to this information, the undersigned hereby certifies that each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS.

VII. **STATEMENT UNDER 37 C.F.R. 1.704(d)**

The undersigned hereby states that:

each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this IDS.

VIII. PAYMENT OF FEES (check only one box)

A. A check in the amount of \$180.00 is enclosed for the above identified fee.

B. Please charge Deposit Account No. 08-0750 in the amount of \$180.00 for the above-indicated fee. A duplicate copy of this paper is attached.

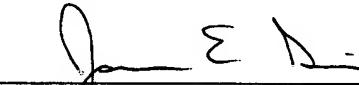
The above references are being cited only in the interest of candor and without any admission that they constitute statutory prior art, contain matter which anticipates the invention, or which would render the same obvious, either singly or in combination, to a person of ordinary skill in the art. Furthermore, this Supplemental Information Disclosure Statement shall not be construed as a representation that a search has been made.

If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 08-0750.

Please charge any additional fees or credit any overpayment pursuant to 37 C.F.R. § 1.16 or § 1.17 to Deposit Account No. 08-0750.

Respectfully submitted,

Dated: May 12, 2005

By: 
James E. Davis
Reg. No. 47,516
Harness, Dickey & Pierce, P.L.C.
7700 Bonhomme, Suite 400
St. Louis, MO 63105
(314) 726-7500

JED/jpg/cml



FORM HDP-1449 (Based on Form PTO-1449)

PATENT AND TRADEMARK OFFICE
INFORMATION DISCLOSURE CITATION
 (Use several sheets if necessary)

Sheet 1 of 7

ATTORNEY DOCKET NO.	SERIAL No.
01507/1/US; 027880A/USA; (6794-000177/US)	10/803,145
APPLICANT	
Karen Siebert	
FILING DATE	GROUP
March 17, 2004	1617

U.S. PATENT DOCUMENTS

Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/Subclass	(If appropriate) Filing Date
1.		4,233,299	11/10/1980	Trummlitz et al.	514/226.5	
2.		4,885,367	12/5/1989	Yoshikawa et al.	546/216	
3.		5,344,991	9/6/1994	Reitz et al.	568/34	
4.		5,466,823	11/14/1995	Talley et al.	548/377.1	
5.		5,474,995	12/12/1995	Ducharme et al.	514/241	
6.		5,521,207	5/28/1996	Graneto, Matthew J.	514/406	
7.		5,633,272	5/27/1997	Talley et al.	514/378	
8.		5,760,068	6/2/1998	Talley et al.	514/403	
9.		5,840,924	11/24/1998	Desmond et al.	549/323	
10.		5,932,598	8/3/1999	Talley et al.	514/341	
11.		5,945,539	8/31/1999	Haruta et al.	548/235	
12.		5,958,978	9/28/1999	Yamazaki et al.	514/567	
13.		5,981,576	11/9/1999	Belley et al.	514/473	
14.		5,994,379	11/30/1999	Bayly et al.	514/367	
15.		5,994,381	11/30/1999	Haruta et al.	514/374	
16.		6,001,843	12/14/1999	Dube et al.	514/277	
17.		6,002,014	12/14/1999	Haruta et al.	548/235	
18.		6,004,948	12/21/1999	Blaschke et al.	514/155	
19.		6,020,343	2/1/2000	Belley et al.	514/309	
20.		6,028,202	2/22/2000	Connolly et al.	548/376.1	
21.		6,034,256	3/7/2000	Carter et al.	549/456	

Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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		01507/1/US; 027880A/USA; (6794-000177/US)	10/803,145
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		March 17, 2004	1617
Sheet 2 of 7			

U.S. PATENT DOCUMENTS						
Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/Subclass	(If appropriate) Filing Date
22.		6,040,320	3/21/2000	Beers et al.	514/341	
23.		6,040,450	3/21/2000	Davies et al.	546/256	
24.		6,046,217	4/4/2000	Friesen et al.	514/347	
25.		6,046,236	4/4/2000	Hamanaka et al.	514/535	
26.		6,057,319	5/2/2000	Black et al.	514/242	
27.		6,071,936	6/6/2000	Dube et al.	514/334	
28.		6,077,850	6/20/2000	Dube et al.	514/311	
29.		6,077,868	6/20/2000	Cook et al.	514/560	
30.		6,077,869	6/20/2000	Sui et al.	514/615	
31.		6,080,876	6/27/2000	Dorziotis et al.	549/319	
32.		6,083,969	7/4/2000	Ferro et al.	514/403	
33.		6,127,545	10/3/2000	Pye et al.	546/286	
34.		6,130,334	10/10/2000	Pye et al.	546/286	
35.		6,133,292	10/17/2000	Wang et al.	514/336	
36.		6,136,831	10/24/2000	Aotsuka et al.	514/367	
37.		6,140,515	10/31/2000	Chen et al.	549/324	
38.		6,153,787	11/28/2000	Rossen et al.	560/187	
39.		6,169,188	1/2/2001	Belley et al.	549/330	
40.		6,180,651	1/30/2001	Nicolai et al.	514/336	
41.		6,204,387	3/20/2001	Davies et al.	546/315	

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Date Considered:

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		March 17, 2004	1617

PATENT AND TRADEMARK OFFICE
INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

Sheet 3 of 7

U.S. PATENT DOCUMENTS						
Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/ Subclass	(If appropriate) Filing Date
42.		6,222,048	4/24/2001	Black et al.	549/60	
43.		6,239,137	5/29/2001	Karmali et al.	514/274	
44.		6,239,173	5/29/2001	Wang et al.	514/473	
45.		6,271,253	8/7/2001	Carter et al.	514/432	
46.		6,291,523	9/18/2001	Fujimoto et al.	514/533	
47.		6,297,282	10/2/2001	Hartmann et al.	514/603	
48.		6,300,363	10/9/2001	Stevens et al.	514/415	
49.		6,303,628	10/16/2001	Nakao et al.	514/307	
50.		6,306,890	10/23/2001	Kalgutkar et al.	514/419	
51.		6,307,047	10/23/2001	Black et al.	544/240	
52.		6,310,079	10/30/2001	Okumura et al.	514/338	
53.		6,310,099	10/30/2001	Fujimoto et al.	514/567	
54.		6,329,421	12/11/2001	Prasit et al.	514/443	
55.		6,340,694	1/22/2002	Joo et al.	514/337	
56.		6,359,182	3/19/2002	Stamler et al.	568/949	
57.		6,362,209	3/26/2002	Haruta et al.	514/374	
58.		6,369,275	4/9/2002	Davies et al.	568/56	
59.		6,376,519	4/23/2002	Reddy et al.	514/341	
60.		6,395,724	5/28/2002	Judice et al.	514/183	
61.		6,432,999	8/13/2002	Talley et al.	514/406	

Examiner:

Date Considered:

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PATENT AND TRADEMARK OFFICE
INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

Sheet 4 of 7

U.S. PATENT DOCUMENTS						
Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/ Subclass	(If appropriate) Filing Date
62.		6,436,967	8/20/2002	Talley et al.	514/341	
63.		6,451,794	9/17/2002	Beswick et al.	514/248	
64.		6,451,858	9/17/2002	Fujimoto et al.	514/567	
65.		6,465,509	10/15/2002	Li et al.	514/460	
66.		6,472,416	10/29/2002	Kolasa et al.	514/403	
67.		6,492,390	12/10/2002	Carter et al.	514/311	
68.		6,492,416	12/10/2002	Shin et al.	514/473	
69.		6,498,166	12/24/2002	Campbell et al.	514/300	
70.		6,512,121	1/28/2003	Talley et al.	548/111	
71.		6,515,014	2/4/2003	Talley et al.	514/438	
72.		6,518,303	2/11/2003	Crespo Crespo et al.	514/459	
73.		6,538,116	3/25/2003	Stamler et al.	534/568	
74.		6,555,563	4/29/2003	Le et al.	514/363	
75.		6,583,321	6/24/2003	Cho et al.	568/33	
76.		6,596,736	7/22/2003	Dube et al.	514/334	
77.		6,599,929	7/29/2003	Cho et al.	514/415	
78.		6,613,790	9/2/2003	Carter, Jeffery S.	514/406	
79.		2003/0165588	9/4/2003	Jia Qi et al.	424/757	
80.		2003/0207897	1/25/2005	DeMello et al.	514/228.2	

Examiner:

Date Considered:

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FOREIGN PATENT DOCUMENTS						
Ref. Desig.	Examiner's Initials	Document Number	Date	Country	Class/ Subclass	Translation Yes No
81.		EP 0 863 134	9/9/1998	Europe	C07C317/24	
82.		EP 1 312 367	5/21/2003	Europe	A61K31/55	
83.		WO 00/23433	4/27/2000	PCT	C07D311/58	
84.		WO 00/24719	5/4/2000	PCT	C07D237/14	
85.		WO 00/25779	5/11/2000	PCT	A61K31/405	
86.		WO 02/20090	3/14/2002	PCT	A61P5/00	
87.		WO 94/15932	7/21/1994	PCT	C07D333/18	
88.		WO 94/27980	12/8/1994	PCT	C07D263/32	
89.		WO 95/00501	1/5/1995	PCT	C07D277/02	
90.		WO 95/15315	6/8/1995	PCT	C07D231/12	
91.		WO 95/15316	6/8/1995	PCT	C07D231/12	
92.		WO 96/03385	2/8/1996	PCT	C07D231/12	
93.		WO 96/03387	2/8/1996	PCT	C07D233/54	
94.		WO 96/03388	2/8/1996	PCT	C07D233/54	
95.		WO 96/03392	2/8/1996	PCT	C07D277/26	
96.		WO 96/09304	3/28/1996	PCT	C07D491/048	
97.		WO 96/16934	6/6/1996	PCT	C07C317/14	
98.		WO 96/24585	8/15/1996	PCT	C07D213/64	
99.		WO 96/25405	8/22/1996	PCT	C07D261/08	
100.		WO 98/03484	1/29/1998	PCT	C07D213/34	

Examiner:

Date Considered:

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		APPLICANT	
		Karen Siebert	
		FILING DATE	GROUP
		March 17, 2004	1617

FOREIGN PATENT DOCUMENTS						
Ref. Desig.	Examiner's Initials	Document Number	Date	Country	Class/Subclass	Translation Yes No
101.		WO 98/47890	10/29/1998	PCT	C07D311/58	
102.		WO 99/10331	3/4/1999	PCT	C07D237/14	
103.		WO 99/10332	3/4/1999	PCT	C07D237/14	
104.		WO 99/11605	3/11/1999	PCT	C07C229/42	

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)		
Ref. Desig.	Examiner's Initials	
105.		Barnes, "Current issues for establishing inhaled corticosteroids as the antiinflammatory agents of choice in asthma," Journal of Allergy and Clinical Immunology, 101(4):S427-33 (1998)
106.		Barnes et al., "Efficacy and safety of inhaled corticosteroids: new developments," Am J Respiratory and Critical Care Medicine, 157:S1-S53 (1998)
107.		Benet et al., "Design and Optimization of Dosage Regimens: Pharmacokinetic Data," in Goodman & Gilman's The Pharmacological Basis of Therapeutics, Ninth Edition (1996), Appendix II, pp. 1707-1711
108.		Bundschuh et al., "In vivo efficacy in airway disease models of roflumilast, a novel orally active PDE4 inhibitor," The Journal of Pharmacology and Experimental Therapeutics, 297(1):280-290 (2001)
109.		College of Physicians and Surgeons of Alberta, "Spirometry & Flow Volume Measurements: Standards and Guidelines" (December 1998)
110.		Fu et al., "The induction and suppression of prostaglandin H2 Synthase (Cyclooxygenase) in Human Monocytes," Journal of Biological Chemistry, 265(28):16737-40 (1990)
111.		Kirchner et al., "Evaluation of the Antiinflammatory Activity of a Dual Cyclooxygenase-2 Selective/5-Lipoxygenase Inhibitor, RWJ 63556, in a Canine Model of Inflammation," Journal of Pharmacology and Experimental Therapeutics, 282:1094-1101 (1997)
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114.		Sterry et al, "Therapy with topical corticosteroids," Arch Dermatol Res, 284[Suppl]:S27-S29 (1992)

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FORM HDP-1449 (Based on Form PTO-1449) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE CITATION <small>(Use several sheets if necessary)</small> Sheet 7 of 7	ATTORNEY DOCKET NO.	SERIAL NO.
	01507/1/US; 027880A/USA; (6794-000177/US)	10/803,145
	APPLICANT	
	Karen Siebert	
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March 17, 2004	1617	

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)		
Ref. Desig.	Examiner's Initials	
115.		The Merck Manual, 17th edition, Sec. 6, Chapter 68, Chronic Obstructive Airway Disorders, Asthma, pages 556-568 (1999)
116.		The Merck Manual, 17th edition, Sec. 6, Chapter 68, Chronic Obstructive Airway Disorders, COPD, pages 568-582 (1999)
117.		The Merck Manual, 17th edition, Sec. 7, Chapter 83-85, pages 669-683 (1999)
118.		Yoshimi et al., "Chemopreventive Effect of N-(2-Cyclohexyloxy-4-nitrophenyl)methane Sulfonamide (NS-398), a Selective Cyclooxygenase-2 Inhibitor, in Rat Colon Carcinogenesis Induced by Azoymethane," Jpn J Cancer Res, 90(4):406-412 (1999)

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